

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



It is recommended that all in-dwelling catheter devices have the potential of fracture, with possible embolization.<sup>4,5</sup> Methods for removal of embolized catheter fragments are also well documented.<sup>6</sup>

In addition the following items are potential complications:

- Sepsis
- Catheter malposition, occlusion, fibrin sheath formation at tip, rupture, erosion, and disconnection
- Exit site infection
- Subcutaneous tunnel infection
- Hemorrhage
- Pneumothorax, hemothorax or hydrothorax
- Vascular thromboses
- Air embolism
- Hematoma
- Vessel trauma
- Cardiac tamponade
- Perforation or laceration of vessels or right atrium
- Endocarditis
- Intolerance to implanted device

#### Caution:

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Read instructions thoroughly before use.
- Contents of package are sterile and non-pyrogenic unless damaged or opened.
- This device is intended for single use only. Do not sterilize.

#### Warnings and Precautions:

- The polyurethane portion of this catheter should not be exposed to prolonged contact with alcohol, alcohol containing substances, or acetone.
- The PolyCath catheter is to be inserted, manipulated and removed only by a qualified licensed physician.
- The medical techniques and procedures recommended in these instructions do not represent all the medically accepted protocols and the physician should use his experience and judgement in determining the acceptable treatment for the patient.
- Use sterile technique when handling or using the catheter.
- Do not clamp the tubing with forceps or sharp instruments.
- Do not nick or cut the catheter or extension assembly.
- The catheter must be filled with saline or an isotonic fluid before insertion to prevent an embolism.
- Catheter must be flushed after blood withdrawals and injections to prevent blockages.
- Prior to infusion of any substance through the catheter, medical personnel should be familiar with and observe all warnings, cautions, contraindications and instructions as specified by the manufacturer of the infused substance.
- Confirmation of catheter placement by x-ray or fluoroscopy is recommended.

#### Catheter Placement:

##### 1. Preparation

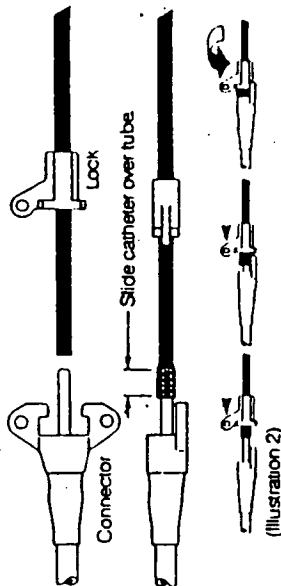
- The catheter must be flushed and filled with intravenous saline or heparinized saline via the extension assembly or blunt needle before placement. Refer to your institutions protocol for determining the heparin concentration and usage.
- Check catheter for flow and patency.

## 2. Catheter Placement

- By surgical cutdown or percutaneous introduction position the distal end of the catheter at the desired site.<sup>7</sup>
- Confirm catheter placement by x-ray or fluoroscopy.
- Using the tunneling trocar create a tunnel to the desired exit site.
- Allow for proper placement of the Dacron cuff.
- The catheter transition from the venipuncture site to the exit site should be smooth and not kink the catheter.

## 3. Catheter Assembly

- Trim the catheter and slide the bayonet locking ring over the catheter.
- Slide the catheter over the connector outlet tube(s) approximately halfway (see illustration 2).



- Slide the bayonet locking ring onto the connector outlet until it contacts the connector body.
- Turn the bayonet locking ring 90° until the suture tab lies flush with the connector base thereby locking the catheter in place.
- Catheter should be visible between the connector and the lock.
- The dual lumen connector (not shown), follows the same assembly technique.
- A suture may be used to secure lock to connector.

## 4. Flow Verification

- Aspirate blood through the catheter to assure patency.
- Irrigate the catheter lumen(s) with intravenous saline or heparinized intravenous saline according to your institutions protocol.
- Attach injection cap(s).
- Secure the venipuncture and exit site as necessary.

## Access and Maintenance Procedures:

### 1. Routine Flush Recommendations:

- Attach a sterile 22 gauge x 1" needle to a 10ml syringe containing 5ml of sterile saline for injection.
- Using aseptic technique, per institutional protocol, prepare the injection cap which is secured to the PolyCath catheter. Inject the saline through the injection cap of the catheter.

### 2. Maintenance

- When the catheter is not being used for infusions or injections, it is recommended that this procedure be performed per institution protocol.
- The internal lumen of the PolyCath catheter must be filled with heparinized saline solution when not being utilized for injections.
- A saline flush must always be performed following an infusion or injection of solutions or medications.

## 3. Aspiration

- After the withdrawal of a blood sample, vigorously flush the catheter with 10-20ml of sterile saline for injection until there is no visible blood in the catheter or the injection cap.
- If blood remains visible within the injection cap, replace the cap using aseptic technique.

## User Checklist

- Do not expose the polyurethane to alcohol
- Use aseptic technique at all times.
- Use only a 10ml or larger size syringe
- Use only solutions that are compatible with the catheter materials.
- Never exceed 25 PSI pressure in the device.
- Be sure saline or heparinized saline remains within the internal lumen of the catheter at all times when not in use
- Flush the catheter after each infusion or injection
- It is recommended that a 20 gauge by 1" needle or smaller is utilized for insertion into the injection cap
- Do not clamp tubing with forceps.

## References:

1. Selinger SI. Catheter replacement of the needle in percutaneous arteriography. *Acta Radiologica* 1953; 39:368
2. Littleford PO. Spector DS. Device for the rapid insertion of a permanent endocardial pacing electrode through the subclavian vein: preliminary report. *Annals Thoracic Surg* 1979; 27:265
3. Aiken DA, Martin JP. The "pinch-off sign": A warning of impending problems with permanent subclavian catheters. *Am J Surg* 1984; 148:633
4. Richardson JC, Grover FL, Trimble JK. Intravenous catheter entol. Experience with twenty cases and collective review. *Am J Surg* 1972; 128:722
5. Robinson RB, Alberty RE, Michels LG, Pederson RW, Rosenkrantz D. Hickman catheter separation. *J Parent Sci Nutr* 1985; 9:754
6. Fisher RG, Ferryro R. Evaluation of current techniques for non-surgical removal of intravascular atrogenic foreign bodies. *Am J Roentgenol* 1978; 130:548
7. Ibid.

## Information:

For further information call or write



Strato Medical Corporation  
123 Bimbal Avenue  
Beverly, MA 01915  
508-927-9419  
Toll Free 800-637-5006

Specifications subject to change without notice

PolyCath is a trademark of Strato Medical Corporation. Patents pending. Strato is a registered trademark of Strato Medical Corporation. Dacron is a registered trademark of E.I. DuPont de Nemours and Co. Inc.

Caution: Federal (U.S.A.) law requires that this device be used in strict accordance with Strato labeling, warnings, contraindications, and instructions. A: adverse effects of these devices

Printed in U.S.A. ©1990 Strato Medical Corporation  
PN102260 Rev. A



Visual Reference Guide for the Placement of the  
Diatek® Cannon™ Catheter

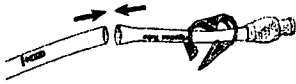
**This brochure does NOT supply complete information for the use of this product. See the Instructions for Use (PN60004) supplied with each Diatek Dialysis Catheter for additional information including Caution and Warning statements that apply to the device.**

Federal Law (USA) restricts the device to sale by or on the order of a physician.  
The Cannon™ Catheter is intended for single use only.  
Do not re-sterilize the catheter or accessories by any method.

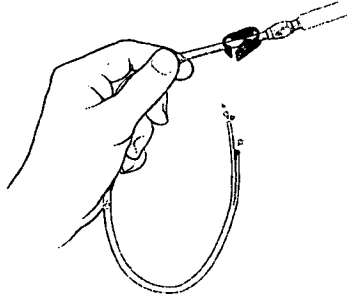
101 N. Chestnut Street, Suite 300  
Winston-Salem, NC 27101  
Phone 336-725-9711 • Fax 336-725-0035  
E-Mail: [info@diatekinc.com](mailto:info@diatekinc.com)

60022 Rev. A

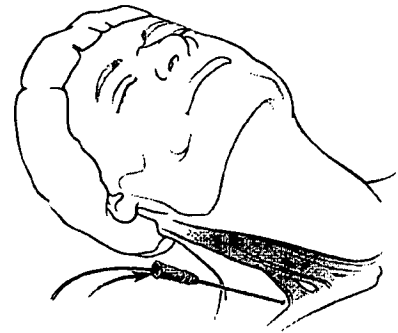
1. Attach irrigation tube to the catheter.



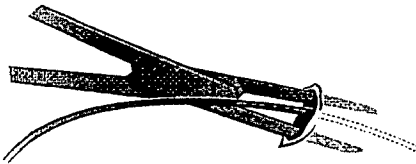
2. Flush and clamp the catheter.



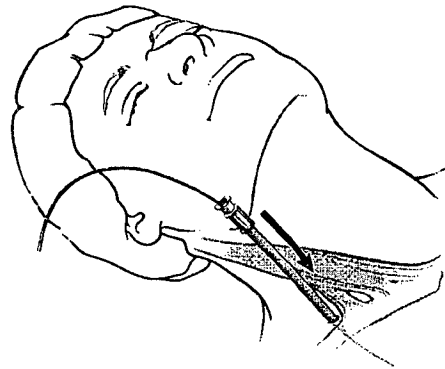
3. Access vessel and determine appropriate catheter length.



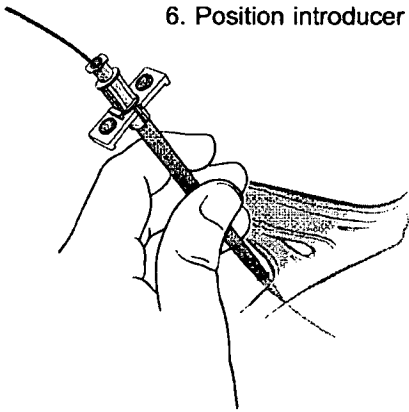
4. Create catheter pocket using blunt dissection.



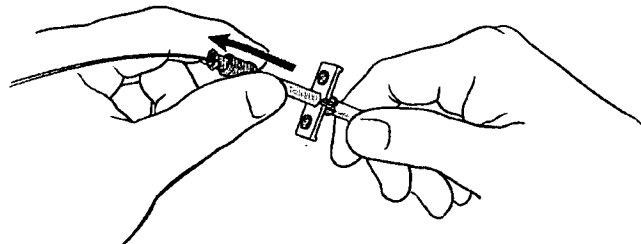
5. Dilate vessel.



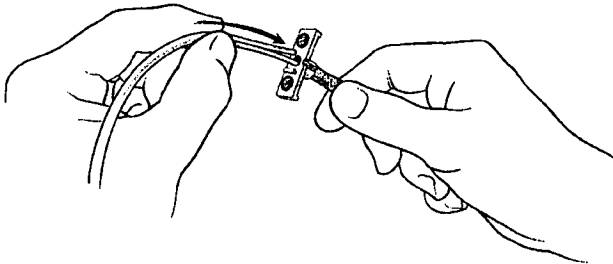
6. Position introducer sheath.



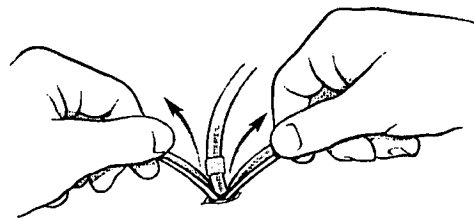
7. Remove dilator from sheath and occlude.



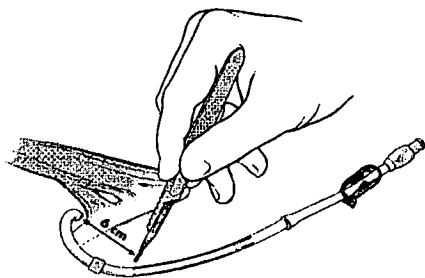
8. Place catheter through sheath into vessel



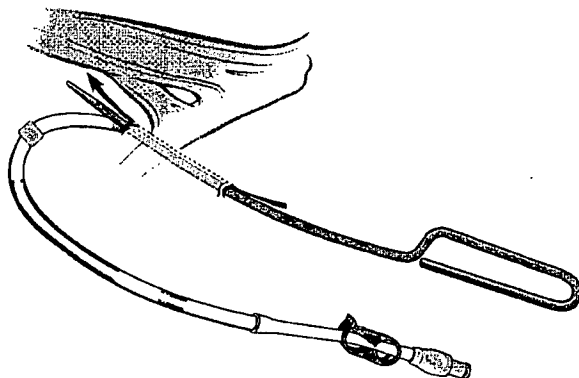
9. Remove peel-away sheath. **Verify that the tips are in the right atrium.**



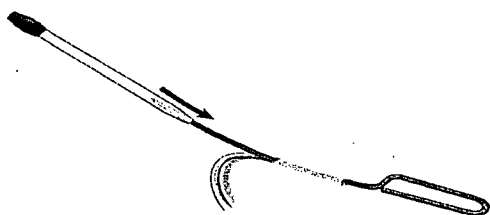
10. Position catheter on the chest with a **gentle curve**, locate exit site mark on catheter (next to cuff) and make a small incision.



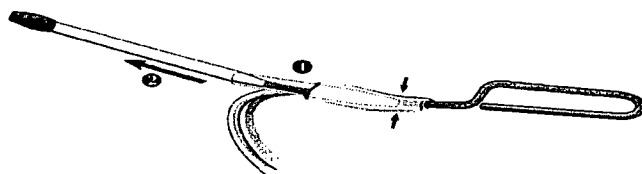
11. Precurve the tunneller and create the tunnel tract.



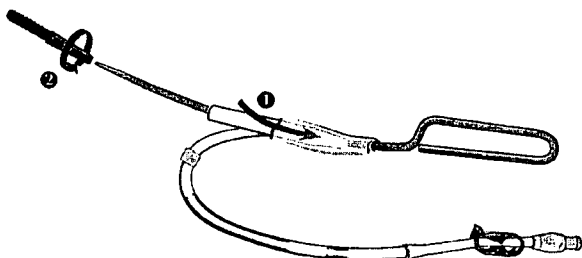
12. Dilate the tunnel tract. **Do not pass through the exit site**



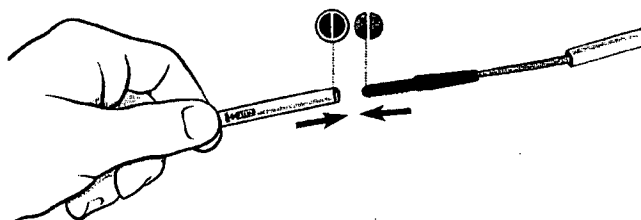
13. Insert to cuff position (1) Remove the dilator (2).



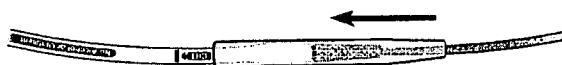
14. Place tunneller sheath (1) over tunneller (optional). Attach catheter connector to tunneller tip.



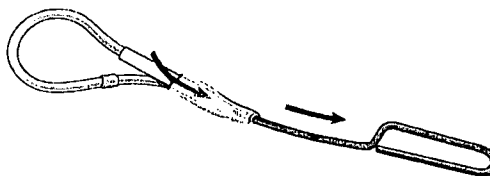
15. Clamp catheter proximal to the cut line and remove irrigation tube. Align prongs of the catheter connector and attach.



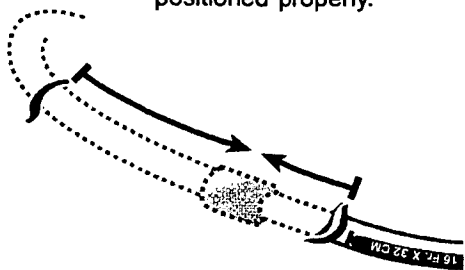
16. Slide tunneller sheath over connection (optional).



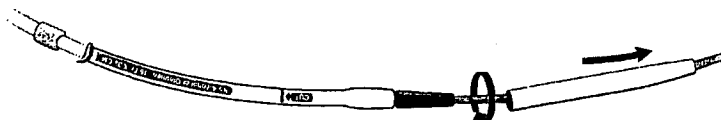
17. Gently pull the catheter through the tunnel tract.



18. Use the exit site mark on the catheter to assure that the cuff is positioned properly.



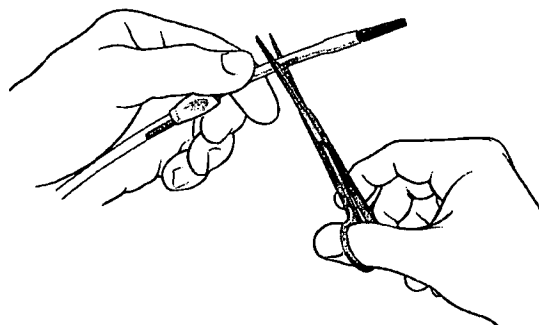
19. Remove tunneller and sheath from the catheter connector.



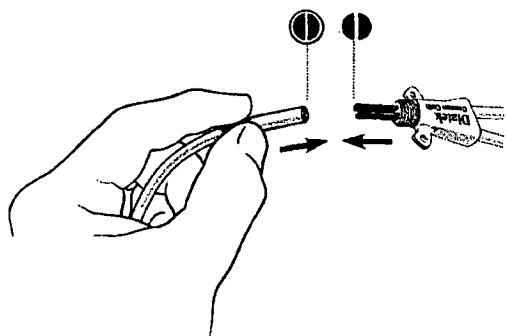
20. Place **compression adapter and sleeve** onto the catheter.



21. Pinch the catheter and cut at the cut line.



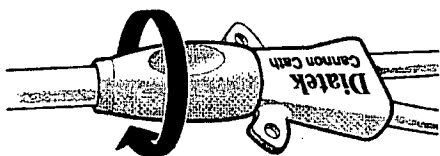
22. Align the catheter with the connection assembly (red to red and blue to blue). Push the catheter completely onto the cannula.



23. Slide the compression adapter forward, with the sleeve inside.



24. Screw the compression adapter onto the threaded section of the connection assembly until **no threads are visible**. Do not over tighten.



25. Secure the catheter to the skin using the suture wings.

